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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,917	10/12/2004	Yoshinori Amano	28951.5346	4324
53067 7590 12/31/2008 STEPTOE & JOHNSON LLP 1330 CONNECTICUT AVE., NW WASHINGTON, DC 20036				
EXAMINER				
WRIGHT, PATRICIA KATHRYN				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/510,917

Applicant(s)

AMANO ET AL.

Examiner

P. Kathryn Wright

Art Unit

1797

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-26 and 34-36 is/are rejected.
- 7) ☒ Claim(s) 27-33, 37-50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 17, 2008 has been entered.

Status of the Claims

2. This action is in response to papers filed December 17, 2008 in which claims 24, 27, 29, 32, 41, 46, 48 and 50 were amended.

The amendments have been thoroughly reviewed and entered. Any objection/rejection not repeated herein has been withdrawn by the Office.

Claims 1-50 are pending. Claims 1-23 are withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 recites "when the operating part is moved into the device body". This conditional statement does not find antecedent basis in the claim 24. The operating

part is outside the device, for operating the sensor sending out mechanism, thereby ejecting a biosensor from the sensor ejecting port. That is, claim 24 does not establish the operating part is moved into the device body. In addition, claim 34 recites "the electrical circuit within the device body". There is no antecedent basis for the electrical circuit.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 24 and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Markart et al., (US Patent No. 6,151,110), hereinafter "Markart".

Markart teaches a biosensor dispensing device comprising a biosensor cartridge 54 for storing a stacked plurality of biosensors 10 and including a sensor ejecting means (feed dog 70) for ejecting a biosensor from the cartridge via a sensor ejecting port 56 (see Fig. 5). The sensor ejecting port 56 is located in a wall of the cartridge facing tips of such biosensors. The port is closed via sealing edges 80 except when such biosensors are being ejected.

The Markart device also includes a biosensor dispensing device body 32 comprising a cartridge storing chamber for detachably (via screws 74) holding the biosensor cartridge 54.

Markart teaches a sensor sending out mechanism (actuating lever 62) for driving the sensor ejecting means 70 in the biosensor cartridge 54. Markart also teaches a sensor conveying mechanism 82, 86, 90, 98 for conveying an ejected biosensor from the sensor ejecting port to a predetermined test position 48 (see Fig. 6). Lastly, Markart teaches an operating part 36 located outside the device body (see Fig. 1), for the operating the sending out mechanism 62, thereby ejecting a biosensor from the sensor ejecting port.

Claims 34 and 36, as best understood, are directed to the manner in which the dispensing device is operated. These limitations do not impart patentability to the claims because they are directed to how the device functions; whereas, patentability in an apparatus claim is determined by the structure of the device.

As to claim 35, Markart inherently teaches a power source (means for powering) for the device that is driven when the biosensor is in the test position in order to operate the light receiving and light emitting elements 52, 50.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markart (US Patent No. 6,151,110), hereinafter "Markart '110, in view of Markart (US Patent No. 6,200,442), hereinafter "Markart '442.

Markart '110 teaches a measuring device with a measuring opening through which optical or electrical sensors sense the test field of a test section of a biosensor (see abstract). However, Markart '110 does not specifically teach the measuring device including a conducting means for connecting electrodes on the biosensor in such test position and for transmitting electrical data from the biosensor to an electrical circuit within the body. However, measuring devices for the electrical measurement of biosensors for determining the concentration of liquid substances on the biosensor are well known in the art.

Markart '442 teaches a biosensor measuring device 10 including a conducting means for connecting electrodes 26 on the biosensor 18 in the test position and for transmitting electrical data from the biosensor to an electrical circuit within the body (see col. 3, lines 5 et seq.)

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in Markart '110 the electrical biosensor measuring device of Markart '442 since electrical biosensor measuring devices are well known for accurately determining the concentration of analytes in liquid substances.

Regarding claim 26, the biosensor dispensing devices of both Markart '110 and Markart '442 include a display unit 38, 14, respectively. The display in both references is located on an exterior surface of the device body and configured to receive electrical data and displays data from the electrical circuit.

Allowable Subject Matter

11. Claims 27-33 and 37-50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter. As discussed above, Markart does teach a biosensor dispensing device comprising a cartridge storing chamber detachably holding a biosensor cartridge for storing a plurality of biosensors in a case in a stacked manner and including sensor send-out means for sending out the biosensor in the case one by one and discharging

the biosensor from a sensor ejecting port opened at the case. The Markart device includes a sensor sending out mechanism for driving the sensor send- out means in the biosensor cartridge, wherein the cartridge storing chamber can hold the biosensor cartridge including a cylindrical rotating member and a sliding member sliding with the rotation of the rotating member to push the rear end of the biosensor as sensor send-out means; the sensor sending out mechanism includes a rotating means for rotating the rotating member of the biosensor cartridge, and the operating part is configured so as to move the sensor sending out mechanism with a forefinger while gripping the body with one hand.

However none of the known prior art, including Markart, teaches or suggests the specific limitations set forth in claims 27 or 46.

Response to Arguments

12. Applicant's arguments with respect to claims 24-50 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is (571)272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. Kathryn Wright/
Examiner, Art Unit 1797